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10/092,489	03/08/2002	Barbara L. Merboth	X-9353	1281

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EXAMINER

FOSTER, JIMMY G

ART UNIT

PAPER NUMBER

3728

DATE MAILED: 02/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/092,489

Applicant(s)

MERBOTH ET AL.

Examiner

Jimmy G Foster

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13, 32 and 35 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 10, 11, 14-19, 21, 22, 24, 25, 28-31, 33, 34, 36 and 37 is/are rejected.
- 7) ☒ Claim(s) 7, 8, 26 and 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

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1. This action is not made final in view of new grounds of rejection applied against subject matter previously held to be allowable.

2. It is noted that in each of claims 22 and 37 the insert member is introduced in the claim as intended use in the paragraph of the claim regarding the blister container, and the paragraph of the claim regarding the insert member begins with "said insert member." This makes the insert member in these claims, and in the dependent claims from claim 22, intended use and not structure in the claim. These claims have been interpreted in this way.

3. Claims 14 and 21, 22, 24 and 37 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 14, the limitations introducing an open-faced cavity, a flange, front and rear end walls, a base and an interior cavity appear to be an indefinite double recitation of these elements already introduced into the claim (by way of claim 1), making it unclear how many of each of these elements there are. Regarding the front and rear end walls, it is unclear what relationship there is with respect to the "walls" already introduced in claim 1.

In claim 21 there is no antecedent basis for more than one of the angularly oriented end walls. Moreover, the claimed angle of orientation is not claimed relative to a particular base orientation (such as the vertical or horizontal) or with respect to the orientation of another element of

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structure. Therefore, the requirement of the limitation of the claim cannot be determined.

In claim 22 the interior cavity of line 4 appears to be an indefinite double recitation of the open-faced cavity in line 2, inaccurately making the blister container appear to be compartmented. Claim 37 has the same kind of problem.

4. Claims 13, 32 and 35 are allowable. Regarding claim 35 and the limitation regarding one end of each of the flanges which extends further outward than the other portions of the flanges, this is not read on by Cohen et al. Although plural corners of the flange of each of the containers of Cohen et al may arguably extend further outwardly than the flange sides, due to the corner dimension being larger, so that each of three or four corners extend outwardly apparently equally, such corners do not meet the limitation of claim 35 (also see objected claim 12). Claim 35 calls for one end extending further outward than the other portions of the flange. The examiner sees that the only reasonable interpretation of "the other portions" is "all other portions", and not just "other portions".

5. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 1-4, 10, 11, 14-19, 21, 22, 24, 31, 34, 36 and 37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cohen et al (4,750,619) in view of Krueger et al (5,868,253). In the reference of Cohen et al, there is provided an outer container at 12, an inner container at 14, an insert member at 50, an inner container flange at 20, an outer container flange at 30, a stepped recess at 32, an inner cover at 24 and an outer cover at 34.

The rectangular inner container includes a base and walls.

The insert member includes a well 59 and integral hinges 62. As can be readily seen in Figure 2 of the reference of Cohen et al, the downwardly open space between a peripheral wall of the well 59 and hinge 62 will define a downwardly directed linear groove, channel, linear depression, shaped depression, trough shaped structure or linear shaped structure. Moreover, the examiner asserts that the shape is substantially V-shaped since one side is inclined (a V does not have to come together at a point). This groove is capable of functioning to hold an appropriately sized and shaped tissue implant adjacent to the base of the inner container, even though the reference certainly does not intend such an implant to be disposed there. However, inasmuch as applicant is only claiming the implant as intended use and not as structure in the claim, the capability of such a groove to hold a tissue implant meets the intended use claimed by Applicant regarding the holding of an implant.

As shown in Figure 2, the groove is defined in cross-section by angled walls, including the wall of well 59, a horizontal wall/base 54, and an inclined wall that extends from the horizontal wall to toward the hinge 62. The wall of well 59 has a different width than the inclined wall. In

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addition, the recess or groove defined by the underside of an upstanding wall 58 may be said to intersect with the groove which is between the wall of well 59 and the hinge 62.

Regarding the subject matter calling for a groove positioned between notched recesses of opposing ends (see as one example claim 2), insofar as claimed, the underside of each side wall 56 of Cohen et al defines another groove, and in Figure 3, the gaps between the surfaces 70 of each side wall 56 and the surface 72 of the side walls 66 define notches on each side of the groove.

Regarding the subject matter calling for a lifting tab extending from a side wall (see as one example claim 3), insofar as claimed, the wall 66 of Cohen et al may be considered to define a lift tab.

Regarding claims 22-24 and 37, the limitations with respect to the insert member are limitations of an insert member that are recited as intended use. The intended use is introduced in the paragraph which concerns the inner container, and the next paragraph which regards the insert member begins "said insert member" and not "an insert member". Inasmuch as the inner container 14 of Cohen et al includes an inner cavity, it is inherently capable of holding an insert member such as that claimed by Applicant as intended use, and therefore the limitations regarding the insert member are met by the capability of the inner container 14 to hold such an insert member.

Although the reference of Cohen et al does not explicitly indicate whether the covers 24 and 34 are permeable or impermeable, the reference of Krueger et al at col. 4, lines 52-59 suggests that the inner and outer covers

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(24,34) may be made permeable, as with permeable polyolefin, for the purpose of permitting the contents of the sealed containers to be sterilized, such as by a steam. Accordingly, it would have been obvious in view of Krueger et al to have made the covers of the containers of Cohen et al permeable to sterilize the contents of the containers through the covers.

In addition, the reference of Krueger et al, at 48 and disclosures thereof, suggests that the inner cover (24) for an inner container may be provided with a tab (48) for pulling the cover from the inner container to open the container. Accordingly, it would have further been obvious in view of Krueger et al to have provided a tab on the inner cover 24 of Cohen et al for pulling the cover from the container to open the container.

Regarding claim 21, the reference of Cohen et al already teaches in Figure 4 the general condition regarding incline of the walls of the inner container 14. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Accordingly, inasmuch as the general condition of inclined walls is already taught in the reference of Cohen et al (in Fig. 4), to have discovered a particular workable range for the angle of incline would have been obvious.

7. Claims 6, 25, 28-30 and 33 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cohen et al (4,750,619) in view of Debs et al (6,622,864). In the reference of Cohen et al, there is provided an outer container at 12, an inner container at 14, an insert at 50, an inner

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container flange at 20, an outer container flange at 30, a stepped recess at 32, an inner cover at 24 and an outer cover at 34.

The inner container includes a base and walls.

The insert includes a well 59 and integral hinges 62. As can be readily see in Figure 2 of the reference of Cohen et al, the downwardly open space between a peripheral wall of the well 59 and the hinge 62 will define a downwardly directed linear groove, channel, linear depression, shaped depression, trough shape or linear shaped structure. Moreover, the examiner asserts that the shape is substantially V-shaped since one side is inclined (a V does not have to come together at a point). This groove is capable of functioning to hold an appropriately sized and shaped tissue implant adjacent to the base of the inner container, even though the reference certainly does not intend such an implant to be disposed there. However, inasmuch as applicant is only claiming the implant as intended use and not as structure in the claim, the capability of such a groove to hold a tissue implant meets the intended use claimed by Applicant regarding the holding of an implant.

As shown in Figure 2, the groove is defined in cross-section by angled walls, including the wall of well 59, a horizontal wall/base 54, and an inclined wall which extends from the horizontal wall to toward the hinge 62. The wall of well 59 has a different width than the inclined wall. In addition, the recess or groove defined by the underside of an upstanding wall 58 may be said to intersect with the groove which is between the wall of well 59 and the hinge 62.

The reference of Debbs et al, at 16 and 70 and disclosures thereof, suggests that an outer container cover (16) may be made impermeable and that

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an inner container cover (70) may be made permeable, such as by providing holes 78, for the purpose of making the container combination (12,14) impermeable but providing a means (holes 78) to equalize the pressures between the containers so as to prevent premature separation of the inner cover (70) on the inner container. Accordingly, it would have been obvious in view of Debbs et al to have made the inner cover 24 of Cohen et al permeable and to have made the outer cover 34 impermeable, for the purpose of equalizing the pressures between the containers so as to prevent premature separation of the lid on the inner container (14).

8. Claims 7, 8, 26 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Applicant's arguments with respect to the claim numbers previously rejected have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jimmy G Foster whose telephone number is (703) 308-1505. The examiner can normally be reached on Mon-Fri, 8:45 am - 5:15 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (703) 308-2672. The fax

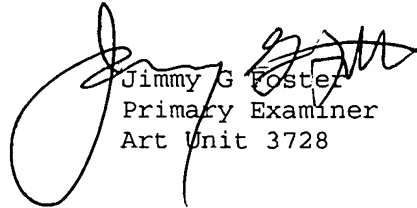
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phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.



Jimmy G Foster
Primary Examiner
Art Unit 3728

JGF
2 February 2004